REMARKS

Information Disclosure Statement (IDS)

An IDS was filed in this application on 3 April 2007, prior to the mailing of the last Office action. Applicant requests that the Office review the IDS.

Rejection under 35 U.S.C. § 103

Claim 7 remains rejected under § 103 over Maloney *et al.* (*Blood*, 1997) in view of Press *et al.* (*Lancet*, 1995), Kaminski *et al.* (*JCO*, 1996), Kaminski (U.S. Patent No. 6,287,537), and Wahl *et al.* (ASCO abstract, 1998).

Applicant renews the arguments stated in the reply filed on 3 January 2007. Additionally, applicant respectfully submits that the Office credits the Kaminski '537 reference with teachings that it does not set forth.

Kaminski '537 does not, as the Office suggests, describe any patients who are refractory to treatment with an unlabeled anti-CD20 antibody. At pages 3-4 of the Office action, the Office cites col. 21, lines 40-54 to support two points. The Office's first point is that one sentence should be read to teach that some patients do not respond to unlabeled antibody. However, this sentence appears in a paragraph that begins, "The antibody moiety of the ^{131}I-B1 conjugate may also be partly responsible for antitumor effects." The entire paragraph relates to evidence that the B1 antibody *per se* exhibits antitumor activity. The fact that some patients may have exhibited a *slower* response to the B1 antibody, as Kaminski '537 teaches, does not contradict the central teaching of the paragraph, namely, that the B1 antibody *does contribute* to the therapeutic response obtained with the combination B1 + ^{131}I-B1 therapy. It is not reasonable to cite a single sentence, removed from the context of the paragraph in which it appears, as teaching exactly the opposite of the point that the paragraph discusses.

The Office's second point is that "the non-radiolabeled anti-CD20 antibody has some anti-tumor effect, [but] it is not efficient … ." If the antibody has "some antitumor effect" in a population of patients, those patients – by definition – are not refractory to the antibody. It does

not matter that the antibody is "not efficient." This teaching refutes the position that the Office wishes to take.

When the teachings of the Kaminski '537 reference are properly assessed, it is clear that the reference provides no motivation to treat any group of nonresponsive patients, including the patients who did not exhibit an observable response during the trial period described by Maloney. Indeed, for the reasons discussed previously, none of the cited references, taken alone or in combination with the others, provides either a reason to treat patients who do not respond to one anti-CD20 in the manner suggested by the Office, or a reasonable expectation that such treatment, if attempted, would be successful.

Applicant respectfully requests that the Office reconsider and withdraw the outstanding rejection.

Double patenting

Claim 7 is provisionally rejected on grounds of obviousness-type double patenting over claims 7-9, 33, 42, 44, 45, 47, and 48 of copending application serial no. 10/196,732 in view of Maloney *et al.* (*Blood*, 1997).

Neither this application nor the '732 application is allowed. Thus, applicant expects that if the copending application is not allowed and the double patenting rejection is the only rejection remaining, this application will be passed to issue in accord with the practice set forth at MPEP § 804, subsection I.B.

Applicant notes that the cited claims of the '732 application are currently withdrawn as directed to nonelected inventions. Should the '732 application be allowed first, and provided that the claims in this application and in the '732 application are substantially the same as the cited claims now pending, without conceding the merits of the rejection, applicant agrees to file a terminal disclaimer in this application over any patent issuing on the '732 application.

Conclusion

Applicant believes that this reply fully responds to the outstanding Office action. Applicant requests that the Office reconsider the outstanding rejections and indicate that the pending claim is allowable.

Should the examiner have any questions, she is invited to contact the undersigned.

Respectfully submitted,

/David L. Fitzgerald/

David L. Fitzgerald, Reg. No. 47,347
Attorney for Biogen Idec Inc.

SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005

tel. (202) 736-8818
fax (202) 736-8711